4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 524, and 558

[Docket No. FDA-2018-N-0002]

# New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 12 new animal drug applications (NADAs) at the sponsor's request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

| File No. | Product Name | 21 CFR Section |
|---|---|---|
| 011-779 | PURINA PIGEMIA 100 (colloidal ferric oxide) | 522.1182 |
| 040-205 | PURINA Horse Wormer Medicated (thiabendazole) | 520.2380a |
| 042-116 | PURINA 6 DAY WORM-KILL Feed Premix (coumaphos) | 558.185 |
| 043-215 | PURINA GRUB-KILL Pour-on Cattle Insecticide (famphur) | 524.900 |
| 046-700 | STATYL Medicated Premix (nequinate) | 558.365 |
| 091-260 | PULVEX WORM CAPS (piperazine phosphate monohydrate) | 520.1804 |
| 097-258 | PURINA BAN-WORM for Pigs (pyrantel tartrate) | 558.485 |
| 102-942 | PULVEX Multipurpose Worm Caps (dichlorophene, toluene) | 520.580 |

| | | |
|---|---|---|
| 113-748 | PURINA PIGEMIA Oral (iron dextran complex) | 520.1182 |
| 135-941 | CHECK-R-TON BM (pyrantel tartrate) | 558.485 |
| 136-116 | PURINA WORM-A-REST™ Litter Pack Premix (fenbendazole) | 520.905d |
| 140-869 | PURINA SAF-T-BLOC BG Medicated Feed Block (poloxalene, 6.6%) | 520.1840 |

Therefore, under authority delegated to the Commissioner of Food and Drugs, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 011-779, 040-205, 042-116, 043-215, 046-700, 091-260, 097-258, 102-942, 113-748, 135-941, 136-116, and 140-869, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Elsewhere in this issue of the *Federal Register*, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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